UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

CONSTRUCTION LABORERS PENSION TRUST OF GREATER ST. LOUIS, on behalf of itself and all others similarly situated, et al. Plaintiffs, vs. NEUROCRINE BIOSCIENCES, INC., GARY A. LYONS, PAUL H. HAWRAN, WENDELL D. WIERENGA, HENRY Y. PAN, RICHARD F. POPS, and WYLIE W. VALE, Defendants.	CASE NO. 07-cv-1111-IEG-RBB ORDER: (1) GRANTING DEFENDANTS' MOTION TO DISMISS THE SECOND AMENDED COMPLAINT (Doc. No. 65); (2) GRANTING PLAINTIFFS LEAVE TO AMEND; and (3) GRANTING IN PART AND DENYING IN PART DEFENDANTS' SECOND SUPPLEMENTAL REQUEST FOR JUDICIAL NOTICE (Doc. No. 67).

Presently before the Court are: (1) defendants' motion to dismiss the second amended complaint in its entirety and (2) defendants' second supplemental request for judicial notice. The lead plaintiffs are Charles N. Seiji and Raymond J. Mertz. Defendants are Neurocrine Biosciences, Inc., Gary A. Lyons, Paul H. Hawran, Wendell D. Wierenga, Henry Y. Pan, Richard F. Pops, and Wylie W. Vale. For the following reasons, the Court: (1) grants defendants' motion to dismiss the second amended complaint; (2) grants plaintiffs leave to amend; and (3) grants in part and denies in part defendants' second supplemental request for judicial notice.

BACKGROUND

A. Factual Background

This action alleges a common scheme and course of conduct by Neurocrine Biosciences, Inc. ("Neurocrine"), its officers, and its directors to defraud investors in violation of Section 10(b) and Section 20(b) of the Securities Exchange Act of 1934. Plaintiffs represent a purported class of investors who purchased Neurocrine stock between February 10, 2005 and June 23, 2006 ("the class period"). Plaintiffs' basic allegations are known to the Court and the parties and need not be repeated herein. In summary, the consolidated amended complaint alleges defendants made material misrepresentations in connection with a New Drug Application ("Application") for a drug called "indiplon." In the Application, submitted November 22, 2004,[1] Neurocrine sought approval by the Food and Drug Administration ("FDA") to market 15 mg of modified release indiplon for the treatment of insomnia.[2] Before and during the class period, defendants expressed optimism about the likelihood of FDA approval. On May 16, 2006, however, Neurocrine announced the FDA had issued a "non-approvable" letter regarding 15 mg indiplon. A non-approvable letter signifies deficiencies in the Application such that approval in the future may require additional data or additional clinical trials. Plaintiffs allege defendants' expressions of optimism about the comprehensiveness of the data were false and misleading because defendants knew the Application would not be approved.

B. Defendants' First Motion to Dismiss

On January 11, 2008, defendants moved to dismiss plaintiffs' consolidated amended complaint on the grounds that it did not sufficiently allege scienter, falsity, and loss causation. Defendants also argued the statements at issue were protected by the safe harbor provisions of the Private Securities Litigation Reform Act (hereinafter "PSLRA"). On May 12, 2008, the Court granted the motion to dismiss. The Court found plaintiffs' allegations of scienter stemming from

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[1]Neurocrine re-filed the Application in May of 2005 due to formatting issues.

[2]The company also developed an immediate-release ("IR") formulation, which the FDA approved in 5 and 10 mg doses. Neurocrine focused primarily on MR indiplon during the class period. As in the Court's Order granting the first motion to dismiss, references herein to "indiplon" are to MR indiplon unless otherwise noted.

the company's decision to "switch" to 15 mg indiplon, insider stock sales, and other allegations, did not support an inference of scienter or falsity. The Court found plaintiffs' allegations that two individuals warned the executive team the Application would not be approved supported an inference of falsity and scienter, but the allegations lacked particularity. The Court explained:

> Without specifics such as the time and place, and the anonymous witness's basis for knowledge and involvement in the conversation, the Court cannot infer defendants secretly credited this warning despite their public expressions of confidence in the Application.

(5/12/2008 Order at 9.) The Court also concluded the FDA's guidelines suggested the amount of data contained in the final Application could be more than adequate, which tended to negate scienter. The Court granted plaintiffs leave to file an amended complaint.

C. Second Amended Complaint

Plaintiffs filed a Second Amended Complaint ("SAC") on June 11, 2008. (Doc. No. 64.) Plaintiffs have added some particularity to the allegations regarding the warning to the executive team. Plaintiffs allege Barbara Finn, the Vice President of Regulatory Affairs, told Confidential Witness 1 (hereinafter "CW 1") that the data supporting the Application for 15 mg indiplon was not sufficient for FDA approval. Plaintiffs allege "CW 1 confirmed that Finn would have also told this to the executive team." (SAC ¶ 82.) Plaintiffs also allege Finn told CW 1 that Paul Jochelson, the Vice President of Clinical Development, told the executive team that the 15 mg Application was not supported by sufficient data.

Plaintiffs allege CW 4, a senior medical director, believed the FDA would likely disregard a large portion of the 20 mg and 30 mg data in determining whether to approve the 15 mg dose. CW 4 was a senior medical director who reported directly to defendant Pan.

Finally, plaintiffs include additional details regarding Neurocrine's decision to pursue FDA approval of 15 mg indiplon rather than approval of 20 or 30 mg formulations.

C. Defendants' Second Motion to Dismiss

On July 8, 2008, defendants filed a motion to dismiss the SAC. (Doc. No. 65.) Defendants also filed a second supplemental request for judicial notice. (Doc. No. 67.) On August 1, 2008, plaintiffs filed an opposition to the motion to dismiss. (Doc. No. 68.) Defendants filed a reply on August 11, 2008. (Doc. No. 69.) The Court found this matter fully briefed and appropriate for

disposition without oral argument pursuant to Local Rule 7.1(d)(1).

DISCUSSION

Legal Standards

1. Rule 12(b)(6) Motion to Dismiss

A motion to dismiss pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure tests the legal sufficiency of the claims asserted in the complaint. Fed. R. Civ. Proc. 12(b)(6); Navarro v. Block, 250 F.3d 729, 731 (9th Cir. 2001). The Court accepts all factual allegations pleaded in the complaint as true, and construes them and draws all reasonable inferences from them in favor of the plaintiffs. Cahill v. Liberty Mutual Ins. Co., 80 F.3d 336, 337-38 (9th Cir. 1996); Mier v. Owens, 57 F.3d 747, 750 (9th Cir. 1995) (citing Usher v. City of Los Angeles, 828 F.2d 556, 561 (9th Cir. 1987)).

2. Pleading Requirements for Private Securities Actions

A claim under Section 10(b) of the Securities and Exchange Act of 1934 or Rule 10b-5 promulgated thereunder has five elements: (1) a misrepresentation or material omission; (2) materiality; (3) scienter; (4) reliance; and (5) causation. McCormick v. Fund Am. Cos., 26 F.3d 869, 875 (9th Cir. 1994).

Pursuant to the Private Securities Litigation Reform Act (hereinafter "PSLRA"), plaintiffs in securities actions must plead fraud with particularity and:

> specify each statement alleged to have been misleading, the reason or reasons why the statement or omission is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed.

15 U.S.C. § 78u-4(b)(1).

Plaintiffs must also plead scienter under the PSLRA's standard: "the complaint shall, with respect to each act or omission alleged to violate this chapter, state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." Id. § 78u-4(b)(2). The required state of mind is one of "deliberate recklessness." In re Silicon Graphics Inc. Sec. Litig., 183 F.3d 970, 975 (9th Cir. 1999). "[R]ecklessness only satisfies scienter under § 10(b) to the extent that it reflects some degree of intentional or conscious misconduct." Id. at 977; see also Nursing Home Pension Fund, Local 144 v. Oracle Corp., 380 F.3d 1226, 1230 (9th Cir.

2004).

The Ninth Circuit "incorporate[s] the dual pleading requirements of §§ 78u-4(b)(1) and (b)(2) into a single inquiry, because falsity and scienter are generally inferred from the same set of facts." In re Read-Rite Corp. Sec. Litig., 335 F.3d 843, 846 (9th Cir. 2003); Ronconi v. Larkin, 253 F.3d 423, 429 (9th Cir. 2001). In assessing whether a plaintiff has sufficiently pleaded scienter, the court must consider "whether the total of plaintiffs' allegations, even though individually lacking, are sufficient to create a strong inference" of scienter. No. 84 Employee-Teamster Joint Council Pension Trust Fund v. Am. W. Holding Corp., 320 F.3d 920, 938 (9th Cir. 2003). "The requirement to plead all the facts with particularity means that a plaintiff must provide a list of all relevant circumstances in great detail." Read-Rite, 335 F.3d at 846 (internal quotations omitted); Silicon Graphics, 183 F.3d at 984. The complaint is sufficient "if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." Tellabs v. Makor Issues & Rights, Ltd., ___ U.S. ___, 127 S. Ct. 2499, 2510 (2007).

Analysis

Defendants' second motion to dismiss again challenges the sufficiency of plaintiffs' allegations of scienter, falsity, and loss causation. Defendants also argue the challenged statements are protected by the safe harbor provisions of the PSLRA.

I. Falsity & Scienter

a. Plaintiffs' New Allegations

Like the consolidated amended complaint, the SAC focuses on the reasons Neurocrine filed an Application for 15 mg indiplon rather than for the 20 or 30 mg doses. As the Court noted in granting the first motion to dismiss, "[r]ather than simply alleging the 15 mg dose reflected a change in the company's approach, plaintiffs must plead 'specific contemporaneous conditions' which 'strongly suggest' defendants knew the 15 mg dose would not be approved." (5/12/2008 Order at 9.) Accordingly, the allegations discussing Neurocrine's decision not to seek approval of higher doses, particularly the reports of CWs 2, 3, and 5, are not relevant and do not support an inference of scienter or falsity.

The parties dispute whether plaintiffs have adequately pleaded that the confidential witnesses were in a position to have personal knowledge of the allegations in the complaint. Because most of the confidential witnesses' reports focus on the dose selection process, which does not pertain to the FDA's non-approval of 15 mg indiplon, this issue is largely moot. CW 4's reports are sufficiently based on his or her personal knowledge. CW 1's representations regarding Finn and Jochelson are the kind of knowledge CW 1 might reasonably possess.

b. Communications with the FDA

In opposition to the motion to dismiss, plaintiffs argue the FDA at some point discussed with Neurocrine the need for additional clinical trials. When the FDA tells a company about the problems with a product, and the company nonetheless continues to make confident statements about the product, courts have inferred scienter and falsity. E.g., Yanek v. Staar Surgical Co., 288 F. Supp. 2d 1110, 1124-25 (C.D. Cal. 2005). In this case, however, the only FDA communications alleged in the SAC pertain to formatting problems with the submission of the Application. (SAC ¶ 91.) Plaintiffs misrepresent the SAC in order to imply communications which cannot be reasonably inferred therefrom. (Plaintiffs' Opposition at 3.) Accordingly, the Court finds plaintiffs have not alleged any communications with the FDA regarding the sufficiency of the data prior to the non-approvable letter.

c. The "Warning" to the Executive Team

Plaintiffs have added additional allegations regarding a warning made to the executive team that the Application was not supported by sufficient data. Plaintiffs now identify by name Finn and Jochelson, the individuals who CW 1 reports made the alleged warning. The SAC does not explain the basis for the warning, who received it, when it was made,[3] how defendants

[3]In their opposition, plaintiffs claim the warnings were given in the second quarter of 2004. This is not based on the facts pleaded in the SAC. Plaintiffs allege discussions took place "prior to the initial filing of the MR [Application] in November 2004"; the warning occurred "as the discussions were taking place"; and Neurocrine selected the dose "before the 15mg trial was initiated in 2Q04." (SAC ¶¶ 82-83.) Nowhere do plaintiffs allege the warnings took place in the second quarter of 2004. Moreover, because they allegedly took place no earlier than the second quarter of 2004, the warnings tend to negate the inference of falsity. See In re Dura Pharms., Inc., Sec. Litig., 548 F. Supp. 2d 1126, 1136 (S.D. Cal. 2008) (hereinafter Dura III) (refusing to infer falsity of statements made when "[t]he filing of the [Application] was still more than six months away, giving Dura adequate time to remedy the deficiencies in its clinical testing . . . . Similarly, statements regarding Dura's expectation of FDA

responded, and why their response was inadequate. As defendants note, plaintiffs do not even allege that Finn actually warned anyone, instead stating Finn "would have" told the executive team that the Application could not be approved. Plaintiffs do not explain the basis for Finn, Jochelson, or CW 4's opinion the data was insufficient. Plaintiffs do not allege CW 4 told anyone, let alone any defendant, that the data was insufficient. Moreover, the SAC does not explain why that opinion was justified based on an understanding of the FDA approval process.[4] Plaintiffs have not pleaded facts from which the Court can infer defendants secretly credited Finn or Jochelson's warnings despite their public expressions of confidence in the Application. There is no showing "that there was a consensus of the management that the risks of [the drug] made the drug unlikely to be approved." In re AstraZeneca Sec. Litig., 559 F. Supp. 2d 453, 471 (S.D.N.Y. 2008). Moreover, plaintiffs' failure to connect any specific individual defendant to Finn and Jochelson's warnings makes the allegations insufficient as to each individual defendant.[5] See Dura III, 548 F. Supp. 2d at 1140-41 (dismissing individual defendants who were not present at the meetings, or did not make any statements); In re Metawave Commc'ns Corp. Sec. Litig., 298 F. Supp. 2d 1056, 1073 (W.D. Wash. 2003) (noting the insufficiency of confidential witness's statement that two

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approval were not materially false while Dura continued to evaluate data from recently completed clinical trials.").

Plaintiffs also claim Finn and Jochelson must have been aware of the other planned studies at 15 mg at the time they warned the executive that the data was insufficient. There is no basis for this inference in the SAC.

[4]Plaintiffs argue defendants later admitted to violating guidelines of the International Conference on Harmonisation of the Technical Requirements for Registration of Pharmaceuticals for Human use ("ICH"). Plaintiffs do not, however, explain what those guidelines required. Plaintiffs do not identify which defendants knew and understood how the FDA would apply the guidelines to the indiplon Application. Finally, plaintiffs do not explain why the defendants must have believed the FDA would find the indiplon Application insufficient. Defendants informed the market that they expected to meet the ICH guidelines by using data from other concentrations and formulations (i.e., IR versus MR) during a conference call on June 24, 2003 (Defendants' Exhibit AQ.) Plaintiffs continue to fail to explain why defendants' failure to accurately predict the FDA's decision "is not merely the difference between two permissible judgments, but rather the result of a falsehood." DeMarco v. DepoTech Corp., 149 F. Supp. 2d 1212, 1232 (S.D. Cal. 2001) (internal citations omitted).

[5]CW 6 reports Pan "attended meetings with members of the executive team." SAC ¶ 81. Although the SAC mentions these meetings in the same paragraph as the executive team meetings at which the alleged "warnings" were made, it is not clear that CW 6 and CW 1 are reporting about the same specific meetings or even the same type of meeting in general. It also remains wholly unclear who the "executive team" refers to. These allegations are not sufficient as to any individual defendant.

individual defendants "would presumably be among the 'Company executives' who received these reports.")

d. Totality of the Allegations

The only allegations probative of scienter and falsity are plaintiffs' allegations that three individuals at Neurocrine, none of whom are defendants, believed the data was insufficient. As discussed herein and at length in the Court's Order granting defendants' first motion to dismiss, these allegations do not satisfy the heightened pleading standard of the PSLRA.

II. Loss Causation

Plaintiffs adequately allege loss causation. (See 05/12/2008 Order at 18.) If the SAC adequately alleges falsity and scienter, these allegations could support a reasonable inference of loss causation under the more lenient pleading standard of Rule 8 of the Federal Rules of Civil Procedure. See In re Daou Sys., Inc., 411 F.3d 1006, 1025 (9th Cir. 2005) (requiring plaintiff to show "some causal connection" between the fraud and the securities transaction in question); In re Immune Response Sec. Litig., 375 F. Supp. 2d 983, 1024 (S.D. Cal. 2005) (noting Rule 8 applies to loss causation).

III. PSLRA Safe Harbor

The new allegations in the SAC have not presented materially different statements which would alter the Court's analysis with respect to the safe harbor provisions of the PSLRA. (See 5/12/2008 Order at 15-18.)

IV. Leave to Amend

The Court may dismiss a complaint without granting leave to amend only if it appears with certainty the plaintiff cannot state a claim and any amendment would be futile. See Fed. R. Civ. P. 15(a) (stating that leave to amend "shall be freely given when justice so requires"); DeSoto v. Yellow Freight Sys., Inc., 957 F.2d 655, 658 (9th Cir. 1992); Schreiber Distrib. Co. v. Serv-Well Furniture Co., 806 F.2d 1393, 1401 (9th Cir. 1986) (stating "leave to amend should be granted unless the court determines that the allegation of other facts consistent with the challenged pleading could not possibly cure the deficiency").

Plaintiffs have requested leave to amend. Because of the exacting pleading standards in

securities cases, the Court will give plaintiffs another opportunity to adequately plead scienter and falsity. If the third amended complaint does not meet the standards set forth in this Order, the Court will not be inclined to grant an additional opportunity to amend.

IV. Request for Judicial Notice

Defendants have filed a supplemental request for judicial notice, which plaintiffs do not oppose.[6] First, defendants request the Court take judicial notice of an FDA/ICH guideline document, Exhibit AU, entitled "Guidance for Industry: The Extent of Population Exposure to Assess Clinical Safety: For Drugs Intended for Long-Term Treatment of Non-Life-Threatening Conditions." Documents publically available to a reasonable investor during the class period are an appropriate subject of judicial notice. In re Copper Mountain Sec. Litig., 311 F. Supp. 2d 857, 864 (N.D. Cal. 2004). Accordingly, the Court judicially notices Exhibit AU.

Defendants also request judicial notice of several exhibits which the Court found unnecessary to consider in support of the first motion to dismiss. Exhibit E is a copy of the collaboration agreement between Pfizer and Neurocrine. Defendants cite the agreement as support for plaintiffs' allegations, which the Court must accept as true. The Court therefore denies the request for judicial notice of Exhibit E as moot. The Court grants defendants' request for judicial notice of Exhibit AQ, which is a transcript of a conference call in June of 2003. The SAC selectively quotes this transcript (¶ 49), which was publically available during the class period. Exhibit AS is a transcript from a conference call on November 2, 2006, after the end of the class period. Defendants cite the transcript to establish what they were thinking during the class period. Their public representations of their past state of mind are not a proper subject of judicial notice. The Court therefore denies defendants' request for judicial notice of Exhibit AS.

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[6]Rule 201 of the Federal Rules of Evidence allows courts to take judicial notice of matters that are "capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b). The Court may take judicial notice on a motion to dismiss under Rule 12(b)(6). Lee v. City of Los Angeles, 250 F.3d 668, 688-89 (9th Cir. 2001); Silicon Graphics, 183 F.3d at 986.

CONCLUSION

For the foregoing reasons, the Court hereby GRANTS defendants' motion to dismiss the second amended complaint. The Court also GRANTS defendants' request for judicial notice in part and DENIES it in part, as set forth in this Order. The Court GRANTS plaintiffs leave to file an amended complaint within thirty (30) days of the date of this Order. If plaintiffs file an amended complaint, they shall also file a "red-lined" version indicating the changes made. Any motion to dismiss the third amended complaint shall be filed within thirty (30) days of the filing of the third amended complaint.

The Court also DISMISSES defendants Pops and Vale with prejudice, as they are not named in the SAC.

IT IS SO ORDERED.

DATED: September 23, 2008

IRMA E. GONZALEZ, Chief Judge
United States District Court